

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Docket No.: 2305-2-3

Steven C. Quay

Filing Date: October 3, 2000

Group Art Unit: 1614

Serial No.: 09/678,591

Examiner: Dwayne C. Jones

Title: Long-Acting Oxytocin Analogues for the Treatment and Prevention of Breast

Cancer and Psychiatric Disorders

CERTIFICATE OF MAILING OR TRANSMISSION

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X Supplemental Information Disclosure Statement

X PTO-1449 w/references

X Postcard

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In Re Application of:

Steven C. Quay

Serial No.: 09/678,591

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Filing Date: October 3, 2000

Examiner: Dwayne C. Jones

For: LONG-ACTING OXYTOCIN ANALOGUES FOR THE TREATMENT AND

PREVENTION OF BREAST CANCER AND PSYCHIATRIC DISORDERS

DATE OF DEPOSIT:

May 20, 2004

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I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. Box 1450, ALEXANDRIA, NA 22313-1450

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the references listed on the attached Form PTO-1449 be **reconsidered** by the Examiner and made of record as of the original filing date of March 26, 2001.

Applicant is complying with the January 29, 2004 request of the Examiner to provide a supplemental list, so that all the references originally cited in the March 26, 2001 Information Disclosure Statement may be properly indicated as being considered. Applicant is providing a "clean" PTO-1449 form along with a copy of all the references that were originally lined out by the Examiner as not being considered because of the omission from the file of hard copies of the references.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information disclosed is, or is considered to be, prior art with respect to the present application or material to patentability as defined in 37 C.F.R. §§ 1.56.

Applicant believes that all the references listed on the original Information Disclosure Statement and PTO 1499 were sent to the United States Patent and Trademark Office on March 26, 2001, and therefore does not believe any fees are required in the submission of this Supplemental Information Disclosure Statement. However, should the Office determine that late submission fees are required for the filing of this Supplemental Information Disclosure Statement, Applicant requests that a telephone conference be conducted to expedite resolution by calling the undersigned at (425) 455-5575.

Respectfully submitted,

Dated: May 20, 2004

Jeffrey J. King

Registration No. 38,515

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Bellevue, WA 98004-5901

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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION				Docket Number (Optional) 2305-2-3				Application Number 09/678,591			
(Use several sheets if necessary)				Applicant(s) Dr. Steven C. Quay							
			U.S. P	PATENT DOCUME	NTS						
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	CA	Atke et al., "Uterotonic Activity and Myometrial Receptor Affinity of 1-Deamino-1-Carwba-2-Tyrosine (O-Methyl)-Oxytocin," Acta Endocrinol. 115:155-160, 1987								ne (O-	
	СВ	Boucher et al., "Double-Blind, Randomized Comparison of the Effect of Carbetocin and Oxytocin on Intraoperative Blood Loss and Uterine Tone of Patients Undergoing Cesarean Section," <u>J. Perinatology</u> 18:202-207, 1998									
	СС	Bussolati et al., "Immunolocalization and Gene Expression of Oxytocin Receptors in Carcinomas and Non-Neoploastic Tissues of the Breast," Am. J. Pathol. 148:1895-1903, 1996									
	CD	Cobo, E., "Characteristics of the Spontaneous Milk Ejecting Activity Occurring During Human Lactation," <u>J. Perinat, Med. 21</u> :77-85, 1993									
	CE Cort et al., "Effect of Oxytocin and its Long-Acting Analog on Milk Let-down and Intramammary Pressure in Healthy Lactating Sows," Am. J. Vet. Res. 43:1283-1285, 1982 CF Dansereau et al., "Double-Blind Comparison of Carbetocin Versus Oxytocin in Prevention of Uterine Atony After Cesarean Section," AM. J. Obstet. Gynecol.180:670-676, 1999 CG Engstrom et al., "Oxzytocin Receptor Binding and Uterotonic Activity of Carbetocin and its Metabolites Following Enzymatic Degradation," Eur. J. Pharmacol. 355:203-210, 1998 CH Fay et al., "Oxytocin Does Not Induce A Rise in Intracellular Free Calcium in Human Breast Cancer Cells," Res. Commun. Mol. Pathol. Pharmacol. 103:115-128, 1999								essure in		
									er Cells,"		
	CI	Gonser, M., "Labor Induction and Augmentation with Oxytocin: Pharmacokinetic Considerations," <u>Arch.</u> <u>Gynecol. Obstet.</u> <u>256</u> : 63-66, 1995									
	Cl	Hunter et al.m "Effe Pharmacol. Ther. 5		ı, A Long-Acting C)xyto(cin Analog	on the F	ostpartu	m Uterus," <u>C</u>	ilin.	
EXAMINER				DATE C	ONS	IDERED					
		citation considered, whation if not in conformation						ext comm	unication to	the	

(2-92)Sheet 2 of 3 m PTO-1449 Docket Number (Optional) Application Number 2305-2-3 09/678,591 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary) Applicant(s) Dr. Steven C. Quay Group Art Unit Filing Date 1616 October 3, 2000 **U.S. PATENT DOCUMENTS SUBCLASS CLASS EXAMINER** DOCUMENT DATE NAME FILING DATE INITIAL NUMBER IF APPROPRIATE FOREIGN PATENT DOCUMENTS **SUBCLASS EXAMINER** DOCUMENT DATE COUNTRY CLASS Translation INITIALS* NUMBER YES NO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) DA Ito et al., "Investigation of the Oxytocin Recptor Expression in Human Breast Cancer Tissue Using Newly Established Monoclonal Antibodies," Endocrinology 137:773-779, 1996 Kimura et al., "Expression and Immunolocalization of the Oxytocin Receptor in Human Lactating and Non-DB Lactating Mammary Glands," Human Reprod. 13:2645-2653, 1998 DC Mena, F., "Central Effects of Catecholamines Upon Mammary Contractility in Rats Are Neurally Mediated," Neuroendocrinology 61: 722-730, 1995 DD Murrell, T.G.C. "The Potential for Oxytocin (OT) to Prevent Breast Cancer: A Hypothesis," Breast Cancer Res. Treat. 35:225-229, 1995 DE Murrell, "Epidemiological and Biochemical Support for a Theory on the Causes and Prevention of Breast Cancer," Med. Hypotheses 36:389-396, 1991 DF Nass et al., "The Biology of Breast Cancer," Hematol, Oncol. Clin. North Am., 13:311-332, 1999 DG Newton, N., "The Quantitative Effect of Oxytocin (Pitocin) on Human Milk Yield," Ann. N.Y. Acad. Sci. 652:481-483 DH Norström et al.,k "Contractile Effect of Oxytocin and 1-Deamino-1-Carba-2-Tyrosine (0-Methyl)-Oxytocin in Myometrial Tissue from Non-Pregnant and Term Pregnant Women," Acta Endocrinol. 122:566-568, 1990 DΙ Orhue, A., "Incremental Increases in Oxytocin Infusion Regimens for Induction of Labor at Term in Primigravidas: A Randomized Controlled Trial," Obstet. Gynecol. 83:229-233, 1994 DJ Planchon et al., "Alteration of Prostaglandin E Receptors in Advanced Breast Tumour Cell Lines," Mol. Cell. Endocrinol. 111:219-233, 1995 DK Sapino et al., "Oxytocin Receptor Within the Breast: Biological Function and Distribution," Anticancer Res. 18:2181-2186, 1998 **EXAMINER** DATE CONSIDERED EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609;

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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Form PTO-1449				Docket Number					Application Number 09/678,591		
INFORMATION DISCLOSURE CITATION IN AN APPLICATION											
(Use several sheets if necessary)				Applicant(s) Dr. S	Applicant(s) Dr. Steven C. Quay						
				Filing Date		3, 2000		Group Art Unit 1616			
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		OTHER DOC	UMENTS (Incl	uding Author, Title, I	Date	, Pertinent	Pages, Etc.)				
	EA	Sapino et al., "Oxytocin Enhance Myoepithelial Cell Differentiation and Proliferation in the Mouse Mammary Gland," Endocrinology 133:838-842, 1993 Satin et al., "Factors Affecting the Dose Response to Oxytocin for Labor Stimulation," Am. J. Obstetl. Gynecol. 166:1260-1261, 1992 Satin et al., "High-Dose Oxytocin" 20-Versus 40-Minute Dosage Interval," Obstet. Gynecol. 83: 234-238, 1994 Silcox, et al., "Transfer of Carbetocin into Human Breast Milk," Obstet. Gynecol. 82:456-459, 1993 Taylor et al., "Interaction of Vasopressin and Oxytocin with Human Breast Carcinoma Cells," Cancer Res. 50:7882-7886, 1990 Van Dongen et al., "Ascending Dose Tolerance Study of Intramuscular Carbetocin Administered After Normal Vaginal Birth," Eur. J. Obstet. Gynecol. Reprod. Biol. 77:181-187, 1998 Vilhardt et al., "Interaction of Chymotrypsin with Carbetocin ([1-Deamino-1-Monocarba-2-O-Methyltyrosine]-Oxytocin)," Pharmacol. Toxicol. 81:147-150, 1997									
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